

REMARKS

Claims 30-46 were pending on the mailing date of the outstanding Final Office Action (17 April 2007). In this paper, claim 30 has been amended to include the subject matter of previously pending dependent claim 45, claim 45 has been cancelled without prejudice, and new claims 47-51 have been added. Claims 30-44, 46 and 47-51, therefore, are pending in this application.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the assigned is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The assignee reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the assignee has made any disclaimers or disavowals of any subject matter supported by the present application.

The undersigned attorney wishes to thank the Examiner for engaging in a personal interview on 6 June 2007 to discuss the present Office Action, the John and Collins references, and pending claims 45 and 46. Additionally, this paper constitutes the applicants' Interview Summary. If the Examiner notices any deficiencies with this paper in this regard, she is encouraged to contact the undersigned attorney to correct such deficiencies.

In the 17 April 2007 Office Action, all of the pending claims were rejected. More specifically, the claims were rejected on the following grounds:

- (A) claim 35 was rejected under 35 U.S.C. § 112, second paragraph;

(B) claims 30, 32-35, 39 and 41-44 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,215,088, issued to Normann et al. ("Normann");

(C) claims 30, 32-35, 39 and 41-44 were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,658,299 B1, issued to Dobelle ("Dobelle");

(D) claims 30-41, 38-42 and 44 were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,066,163 issued to John ("John"); and

(E) claims 45 and 46 were rejected under 35 U.S.C. § 102(e) over John or, in the alternative, under 35 U.S.C. § 103(a) over the combination of John and U.S. Patent No. 5,782,873, issued to Collins ("Collins").

A. Response to Section 112 Rejection

Claim 35 was rejected under Section 112 on the ground that it includes an improper Markush group. The applicants respectfully disagree. First, claim 35 is not intended to be a Markush group. Second, claim 35 is sufficiently definite because it includes further defining the behavioral therapy as having the patient engage in at least one of a physical therapy, a cognitive therapy, an activity of daily living, a volitional use of an affected body part, a speech therapy, a visual task, a reading task, a memory task, a comprehension task and an attention task. The behavioral therapy of claim 35 accordingly includes having the patient engage in a single one, or any combination, of the foregoing activities. The scope of the claim 35, therefore, is definite under Section 112, paragraph 2.

B. Response to Section 102(e) Rejection – Normann

Claims 30, 32-35, 39 and 41-44 were rejected under 35 U.S.C. § 102(b) over Normann. Claim 35 has been amended to include the subject matter of claim 45, which was not subject to this rejection, and claims 32-35, 39 and 41-44 depend from claim 35. Therefore, this rejection is now moot and these claims will be discussed below in Section E regarding the rejection of previously pending claim 45 under Section 102 over John or, in the alternative, under Section 103 over the combination of John and Collins.

C. Response to Section 102(e) Rejection – Dobelle

Claims 30, 32-35, 39 and 41-44 were rejected under 35 U.S.C. § 102(b) over Dobelle. Claim 35 has been amended to include the subject matter of claim 45, which was not subject to this rejection, and claims 32-35, 39 and 41-44 depend from claim 35. Therefore, this rejection is now moot and these claims will be discussed below in Section E regarding the rejection of previously pending claim 45 under Section 102 over John or, in the alternative, under Section 103 over the combination of John and Collins.

D. Response to Section 102(e) Rejection – John

Claims 30, 32-35, 39 and 41-44 were rejected under 35 U.S.C. § 102(b) over John. Claim 35 has been amended to include the subject matter of claim 45, which was not subject to this rejection, and claims 32-35, 39 and 41-44 depend from claim 35. Therefore, this rejection is now moot and these claims will be discussed below in Section E regarding the rejection of previously pending claim 45 under Section 102 over John or, in the alternative, under Section 103 over the combination of John and Collins.

E. Response to Section 102 and Section 103 Rejections – John and Collins

Claims 45 and 46 were rejected under Section 102 over John alone or, in the alternative, under Section 103 over the combination of John and Collins. Although claim 45 has been canceled, claim 35 has been amended to include the subject matter of previously pending claim 45. As such, amended claim 35 and claim 46 were discussed during the interview on 6 June 2007 in light of John alone or in combination with Collins.

During the interview, it was noted that claims 35 and 46 are directed toward a combination of subthreshold electrical stimulation, behavioral therapy, and discontinuing the electrical stimulation delivered to the cortical stimulation site after a therapy period expires. In claim 35, for example, the electrical stimulation is applied to the stimulation site at a level "below a threshold level of neurons at the stimulation site." Claim 35 is patentable over John alone or in combination with Collins because John teaches away from applying electrical stimulation at a level below a threshold level of neurons at the

stimulation site. John is directed toward an adaptive brain stimulator that uses a feedback process based on a "measured present state" in response to electrical stimulation that is intended to cause the neurons to fire. To reach this objective, John discloses electrically stimulating the brain either with or without pharmaceutical stimulation, measuring the "present state" using EEG or evoked potentials, and comparing the measured present state with a reference state. John teaches that the electrical stimulation alone should cause a specific pattern of cellular firing that can be quantified to come up with the "measured present state," and thus John's electrical stimulation is suprathreshold stimulation rather than subthreshold stimulation. John specifically states that the determination of a "present state" involves the evaluation of the components of the specific *neural response to the stimulation* known as an evoked potential (col. 13, ln. 66, to col. 14, ln. 2). Moreover, one of John's primary applications is treating comatose patients, and the applicants submit that one of John's primary purposes would be destroyed if his method was modified to apply electrical stimulation at a subthreshold level because suprathreshold stimulation is necessary to generate the feedback for measuring the present state in such situations. John further states that parameters of the autonomic nervous system, such as EKG, ECG, and blood pressure, should be monitored during stimulation procedures to ensure that the stimulation does not adversely affect vital functions (col. 5, lns. 15-23). John accordingly teaches delivering electrical stimulation in a manner that itself can adversely affect vital functions (e.g., EKG), and thus it follows that John teaches the application of suprathreshold electrical stimulation. Claim 35, therefore, is patentable over John alone or in combination with Collins.

The applicants also respectfully disagree with the Examiner's application of pharmacological stimulation as described by John with respect to the present claims. The portion of John at column 13, lines 14-25, cited by the Examiner is directed toward using a pharmacological stimulator "contingent upon a specific pattern of cellular firing or upon an increase of a specific frequency in the EEG." Because John discloses using suprathreshold electrical stimulation to cause the neuronal firing pattern that would be detected by EEG, and the administration of the pharmacological stimulator is contingent

upon the occurrence of the specific firing pattern, it follows that John teaches administering a pharmacological stimulator after applying suprathreshold electrical stimulation to increase the chances that subsequent suprathreshold electrical stimulation will repeat the "firing" pattern. This statement in John directly teaches away from the subthreshold stimulation of claim 35 because John's electrical stimulation must already fire the neurons to create the specific pattern of cellular firing (i.e., the electrical stimulation is suprathreshold) as a condition precedent to even administering the the pharmacological stimulator. Therefore, John teaches chemically augmenting neural firing activity to enhance the repeatability of the suprathreshold firing pattern in the presence of suprathreshold electrical stimulation. The Examiner's application of John to subthreshold electrical stimulation is accordingly incorrect and inapposite to the teachings of John.

Claims 31-44 are patentable over John alone or in combination with Collins as depending from claim 35 and for the additional features of these dependent claims. Claim 46 is patentable over John alone or in combination with Collins for reasons that are analogouse to those explained above with respect to claim 35. Therefore, the applicants respectfully request withdrawal of the rejection of claims 30-44 and 46.

New claims 48-51 are further patentable over John, either under Sections 102 or 103, because John does not disclose or suggest having the patient intentionally use a body part in a manner that reinforces the neural function. The applicants do not concede that John discloses any behavioral therapy as claimed. Nonetheless, for the sake of argument, even if John's auditory, visual or tactile stimulators are considered behavioral therapy, they do not cause the patient to intentionally use the affected body part to reinforce the electrical stimulation. John discloses that his system is useful for treating comatose patients, and such patients cannot intentionally use the peripherally stimulated body part. Rather, the peripheral auditory, visual or tactile stimulation taught by John enables non-volitional transient evoked potentials. Claims 48-51 are accordingly further patentable over John.

In light of the foregoing, all the pending claims comply with 35 U.S.C. § 112 and are patentable over the cited art. The applicants accordingly request reconsideration of the application and respectfully submit that all the pending claims are in condition for allowance. If Examiner Alter has any questions or believes a teleconference would further expedite prosecution of this application, she is encouraged to contact the undersigned representative at (206) 359-3258.

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Respectfully submitted,

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